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Food and Drug Administration
Nashville District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

297 Plus Park Boulevard
Nashville, TN 37217

April 22, 1998

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. Chad D. Holliday, Jr.
President and Chief Executive Officer
DuPont DeNemours and Company
1007 Market Street
Wilmington, Delaware 19898

WARNING LETTER - 98-NSV-10

Dear Mr. Holliday:

During an inspection of your Hydrogen Peroxide manufacturing facility located at 2571 Fite Road, Memphis, Tennessee on March 25-27, 1998, our investigator determined that your Hydrogen Peroxide was adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Although the Current Good Manufacturing Practice (CGMP) regulations under Title 21, Code of Federal Regulations, Parts 210 and 211, apply only to finished dosage form drugs, Section 501(a)(2)(B) of the Act requires that all drugs be manufactured, processed, packed, and held in accordance with CGMP. No distinction is made between bulk pharmaceutical chemicals (your Hydrogen Peroxide) and finished pharmaceuticals, and failure of either to comply with CGMP constitutes a failure to comply with the requirements of the Act.

Our inspection revealed the following deviations from CGMP: failure to validate your manufacturing process, no stability testing program, Hydrogen Peroxide was not tested for impurities, no written packaging and labeling procedures, incomplete master label files, inadequate laboratory and production procedures and a failure to document daily pH meter calibrations.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action including seizure and/or injunction without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations.

If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the correction will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Raymond K. Hedblad

Raymond K. Hedblad
Director, Nashville District

RKH/kl

Enclosures:
21 CFR Part 210 and 211
FDA Guide to Inspection of Bulk Pharmaceutical Chemicals

cc: John R. Wasilik
Plant Manager
DuPont Specialty Chemicals
2572 Fite Road
Memphis, TN 38127